Q On Page 300 of Dr. Nicholson's paper, do you still have that in front of you, --

A Oh yes.

Q --Dr. Ory? The statement about asbestosis deaths about the lower risk population --

A Yes.

Q -- that Dr. Nicholson puts in quotes, do you see that?

A Yes.

Q Of the 27.5 million individuals Dr. Nicholson and the others at Mount Sinai estimated that 18.8 million of them had asbestos exposures higher than two to three fiber years of exposure, correct?

A Yes.

Q Can you explain to the Court what is meant by fiber year of exposure?

A If you work in an environment say that has one fiber per cc concentration on a time-weighted average and you do that for a year, you have one fiber year exposure. If you do it for three years, you have a three-fiber year exposure.

Q And you helped -- you reviewed the slides that we were showing today, correct?

A I created most of them.

Q You created most of them. Turn on the elmo (phonetic) please. Do you recognize this as something you helped create as well?

A Yes.

THE COURT: Could you identify it for the record please?

MR. FINCH: This is a slide that I was given by counsel for the debtor yesterday.

THE COURT: It doesn't have an exhibit number?

MR. FINCH: It doesn't have an exhibit number.

Q Doctor --

THE COURT: Could you mark as --

MS. HARDING: These are our draft slides that we didn't use, but --

MR. BERNICK: I would have a fundamental problem, Your Honor -- this is David Bernick for Grace -- that we have an arrangement that was specifically entered into to provide notice to the other side regarding what might be used. If we're going to have cross examination with respect to these draft slides, then I am no longer in any kind of agreement whatsoever that we'll have an advance exchange of demonstratives.

MR. FINCH: Your Honor, there was never any --

MR. BERNICK: Excuse me. That is a complete breach of an agreement made with counsel. This is now the third time in the last week that there have been express breaches of agreements. Our agreement to that is withdrawn. We will not submit any more unless Your Honor, of course, orders us to.

It's a wholly improper use of an accommodation to counsel.

MR. FINCH: Your Honor, there was never any agreement that you couldn't cross examine an expert based on the draft of his demonstratives. This was -- I'm perfectly happy to forego the exchange of demonstratives. There was never an agreement with that. It was an agreement that you get the draft demonstratives. This is a demonstrative that comes directly out of Dr. Ory's report, the demonstrative, but the statements come in his report and so I think it's perfectly fair on cross examination of an opposing witness to ask him about statements that were in his report that were reduced to graphical form in an exhibit that he helped oversee.

UNIDENTIFIED SPEAKER: I don't care.

MR. BERNICK: And I would further add, Your Honor, that under the stipulation that was entered into in this case in connection with experts, there was to be no discovery with respect to draft reports and this is totally in harmony with exactly the same arrangement. I'm happy not to have any exchange of demonstratives. That is fine with me. This is something I agreed to purely as an accommodation to counsel.

THE COURT: I'm not sure exactly what the point is. I mean the reason that drafts were not being exchanged is because they were drafts. They were not the final witness's presentation. That's why the finals were exchanged, so --

MR. FINCH: Your Honor, this is not his report. Q

Let's put it this way, Dr. Ory, do you have your report?
A I do.
Q Okay, could you turn to Page --
UNIDENTIFIED SPEAKER: (Inaudible).
Q Could you turn to Page 34 of your report?
A Yes.
Q Okay, the report has been marked, for purposes of identification, as ACC FCR 561. Could you show 561, Page 34? There you write Nicholson considered low dose exposures to be between two to three fiber years of cumulative lifetime exposure, correct?
A Yes.
Q All right, he didn't actually call them low dose exposures in the paper. That's your terminology, correct? He called them lower in dose?
A That's true.
Q Okay now, would you agree with me -- you have a statement there that if someone has mesothelioma, the odds are 50 to 1 that he developed it due to an exposure greater than two to three fiber years, correct?
A That's correct.
Q And in the -- and you would agree with me that two to three fiber years is what Dr. Nicholson considered -- an epidemiologists consider as a high dose exposure for asbestos?
MS. HARDING: Object to form.

THE WITNESS: All he said there was this was a lower risk population.

Q Okay, but not a no risk population?

A He called it a lower risk population.

Q Okay, and so if someone has mesothelioma, would you agree with me that it is more likely than not they were exposed to at least two to three fiber years cumulative dose of asbestos?

A If someone -- if you showed me -- it's the way you're constructing your words. If you showed me a person who has mesothelioma and told me nothing more about the person, I would say there's a 98 percent chance that that person had more than a three-fiber year exposure to asbestosis.

Q Three-fiber year exposure to asbestos?

A I'm sorry, to asbestos.

Q Cumulative exposure?

A Cumulative exposure, three fiber years.

Q You still have your report? One of the papers you cite at the back of your report is a paper written in 2004 by Bertram Price and Adam Ware?

A Yes.

Q Okay, could I have ACC 560 please?

MR. FINCH: Your Honor, may I approach the bench and the witness?

THE COURT: Yes.

Q Dr. Ory, do you have the Price and Ware paper in front of

you which has been premarked for identification of ACC 560?
A I do.
Q Okay, the first paragraph in the third sentence, I don't know if they're doctors but Misters or Doctors Price and Ware write, "Mesothelioma projections also provide a foundation for estimating the number of potential lawsuits from persons claiming occupational exposure to asbestos or exposure resulting from use of previously-manufactured asbestos-containing products, do you see that?
A Yes.
Q One of the experts reports who you reviewed in this case is Dr. Mark Peterson, correct?
A Yes.
MR. FINCH: Can I have Peterson's report taped up? Let's put the whole report up, the whole report. Your Honor, may I approach the witness and the bench?
THE COURT: Yes. You don't need to keep asking, Mr. Finch, when you need to show him an exhibit.
MR. FINCH: Okay.
THE COURT: Thank you.
Q Now, you criticize Dr. Peterson's report about -- basically, your testimony here boils down to that whatever he was projecting, it wasn't the number of medically-plausible asbestosis cases, correct?
A Yes.

Q All right, and you're familiar with Dr. Peterson's report because you had to review it in order to do your report, correct?
A Yes.
Q Okay, could you turn to Page 76 in Dr. Peterson's report? It's going to be that page. Do you see that?
A I'm getting there. Just a moment, okay? I'll get there in a minute.

(Pause)

THE WITNESS: Okay, I'm sorry, Page 76?
Q Page 76, do you have that in front of you?
A All right, yes.
Q Do you see Figure 24?
A Yes.
Q That's Dr. Peterson's projection of -- it has Dr. Nicholson's meso forecast and then Dr. Peterson's projection of mesothelioma claims against Grace, correct?
A Yes.
Q You didn't offer any opinion about whether the number of mesothelioma claims he's projecting are medically plausible or not, correct?
A I offer no opinion about that.
Q Okay, and Dr. Peterson is not projecting a flat line, straight number of mesothelioma claims going out for the next 30 years, is he?

MS. HARDING: Your Honor, I'm just going to object because the doctor has already testified that he's not offering opinions about it so I don't know why he's going to ask him about it.

MR. FINCH: Your Honor, this is cross examination. It goes to what he did and what he didn't do and his credibility. I have two more questions on this topic.

THE COURT: I don't know how what Dr. Peterson did or didn't do affects this witness's credibility. That's not a (indiscernible) question.

MS. HARDING: And he also said he didn't suggest claims so I don't know why he's asking him about Dr. Peterson's claims.

MR. FINCH: Okay, his report was submitted as a rebuttal report to Dr. Peterson and Dr. Welch. I don't know why they put him on in their case in chief. He was submitted as a rebuttal -- he was submitted as a rebuttal expert so I think it's fair for me to cross examine him based on what he did and didn't do in his report.

MS. HARDING: Your Honor, his report was submitted as a rebuttal, that it was submitted with respect to certain aspects of Dr. Peterson's report that had clearly to do with diseased cases. It had nothing to do with the projection of claims.

THE COURT: This witness has testified that he did

nothing to predict claims, that he was looking at predictions of actual mesothelioma cases, medical cases that would be diagnosed, not claims that could be filed. He's been very clear about that.

MR. FINCH: Okay, but he said that Dr. Peterson's projections of future asbestosis claims is medically implausible. The point I'm trying to make is that he doesn't believe that Dr. Peterson's projections of mesothelioma claims is medically implausible.

MS. HARDING: He did not offer that testimony, Your Honor. He did not offer an opinion about Dr. Peterson's future claims of asbestosis.

THE COURT: You may ask him if he has an opinion on that subject first. Let's start with that.

Q Okay, is it correct, Dr. Ory, that you don't have an opinion about whether Dr. Peterson's --

THE COURT: You have to state it affirmatively, Mr. Finch, and find out if he does have an opinion. You can't ask him if he doesn't have an opinion. How are we going to know --

Q Dr. Ory, do you have any opinion at all about whether Dr. Peterson's projections of mesothelioma claims are medically plausible?

A I believe in my report on the bottom of Page 3 and the top of Page 5 I restrict my comments to Peterson about asbestosis.

Q Okay.

MR. FINCH: Your Honor, at what point would you contemplate taking a lunch break? I know I have another half hour to go and I'm sure that Mr. Ansbro has questions as well.

THE COURT: Well then this will be fine. We'll take an hour for lunch. We'll reconvene at 1:25.

MR. BERNICK: Could we get an estimate on cross examination? We have Mr. Rodricks -- Dr. Rodricks who's waiting in the wings here.

MR. FINCH: I have another half hour. I'm not sure what John has.

MR. ANSBRO: I'd say up to 45 tops.

MR. BERNICK: Forty-five tops, okay. So we should be able to get Rodricks' direct on at least. I mean --

UNIDENTIFIED ATTORNEY: We'll just deal with that on the break.

MR. BERNICK: Okay, that's fine, Your Honor.

THE COURT: All right, we'll be in recess until 1:25.

(Recess)

THE COURT: Doctor, you're still under oath. Mr. Finch?

Q Good afternoon, Dr. Ory.

A Good afternoon.

Q Turn on the elmo. One of the slides that you showed in your direct examination, Dr. Ory, this is the age-adjusted

death rates from asbestosis?
A That's correct.
Q Okay, may I approach, Your Honor?
THE COURT: Yes.
Q Dr. Ory, do you recognize what has been marked as ACC 571 as something you brought with you to your deposition that demonstrated where you got the figures for the age-adjusted death rates?
A That's correct.
Q This is from the CDC NIOSH occupational deaths due to asbestosis?
A That's correct.
MR. FINCH: Your Honor, I offer 571.
THE COURT: Any objection?
MS. HARDING: Just say what it is again, I'm sorry.
MR. FINCH: Sure, this is what Dr. Ory brought to the deposition, the CDC NIOSH government statistics of deaths from asbestosis. It derives the foundation for the death rates shown in his chart, GG2048.
THE COURT: He copies these numbers onto his chart.
MS. HARDING: No, no, Your Honor, I was trying to figure out -- at first I thought it was an extra page and I was just trying to figure out -- if Dr. Ory has represented that it's the entire part of his exhibit that he offered at the deposition. I don't have any objection. That was me. I'm not

sure if it was part of the exhibit. That's my only question.

UNIDENTIFIED ATTORNEY: I believe it was.

MS. HARDING: He said it was an exhibit at the deposition. That's why I wasn't sure. I thought his exhibit was only one page, but it could have been two.

MR. FINCH: Your Honor, it is the deposition exhibit, the whole three-page document was a deposition exhibit.

MS. HARDING: On that representation, we won't object, Your Honor.

MR. FINCH: Okay.

THE COURT: It's admitted.

Q All right now, the CDC and NIOSH also keep statistics for the occupationally-related mesothelioma deaths, correct?

A They keep statistics on mesothelioma deaths.

MR. FINCH: Okay, and may I approach the witness, Your Honor?

THE COURT: Yes.

MR. FINCH: Your Honor, Exhibit 614 --

Q You have Exhibit 614 in front of you, Dr. Ory?

A I do.

Q And the first two pages are a certification from the United States government that this is a true and accurate copy of records collected and reported pursuant to official government authorities?

A Yes.

Q And then the third page is a page that looks like this?
A Yes.
Q And that's the counts of mesothelioma death in the -- as determined by NIOSH CDC from 1999 to 2004?
A Right, for both sexes.
Q Okay, and it shows 2,484 in 1999?
A That's correct.
Q Rising to 2,657 in 2004?
A That's correct.
Q So if someone read that and said U.S. government statistics show that the mesothelioma count is actually going up, it's been a flat a long time but it's still going up, that's not accurate -- that is accurate based on this government data, correct?
A If they said deaths were going up.
Q Mesothelioma deaths are actually going up?
A Yes.
Q Okay.
A In men and women totaled.

MR. FINCH: Your Honor, I would offer Exhibit 614.

MS. HARDING: No objection, Your Honor.

THE COURT: It's admitted.

Q Now, do you still have 571 with you, Dr. Ory?
A Let's see, the first one you gave me?
Q That's the one that you brought with you to your

deposition.
A Yes.
Q Okay, the first page of that shows the death -- the numbers of deaths and the death rate between 2000 and 2004, right?
A That's correct.
Q Okay, and the third page is this page, shows the deaths from asbestosis and the age-adjusted death rate for each year between 1990 through 2004, correct?
A That's correct.
Q Okay, would you agree with me that the date that -- do you have the understanding the date we're interested in is what was Grace's asbestos liability on the day it went into bankruptcy?
MS. HARDING: Objection. I don't think the foundation --
Q Okay, would you agree with me that the deaths and the age-adjusted death rates were rising between 1990 and 2000?
A Yes.
Q And that the age-adjusted death rates and the total numbers of deaths between 2001 and 2004 are still higher than they were in 1996, 1997, 1998 and 1999?
A We're talking now about 571?
Q That's right.
A I would say that the age-adjusted death rate from 1990 to '99 was trending slightly upwards, that's correct. And what's

the second part of your question?
Q And that it peaked around 2000?
A The death rate?
Q The death rate peaked around 2000?
A Yes.
Q And then the death rate has declined somewhat since 2000 but it's still higher in 2004 than it was in 1999?
A That's correct.
Q And that the numbers of deaths between 2000 and 2004 average around 1,410 a year, correct?
A Yes.
Q And that's not substantially lower than the numbers of deaths in 2000, correct?
A Well, I mean, yeah, the numbers of deaths are slightly lower in 2003 and 4 say than in 2000 and 2001.
Q Okay, and the -- Dr. Nicholson's projections of mesothelioma deaths expected at the mesothelioma incidents the United States would peak in the 2000 and 2004 time period, correct?
A Right.
Q And it declined gradually thereafter, correct?
A You're talking about mesothelioma deaths?
Q Mesothelioma deaths.
A Yes, he had them peaking around 2002.
Q And then the curves that we showed in your demonstratives

showed that the shape of Dr. Nicholson's projections over the next 20 some years is basically a long, slow decline for mesothelioma?

A Well, it declined slowly at first and then it picks up speed.

Q It picks up speed in --

A Yes.

Q -- twenty or thereabouts.

A It picks up speed every five-year interval.

Q Every five-year interval after 2002?

A Right.

Q But there's still -- he still is projecting 900 deaths from mesothelioma in the year 2027?

A Right, which I would say then marked down by 20 percent.

Q Okay, if you're just looking for men, but if you're looking for men and women, you wouldn't mark it down by 20 percent?

A Well, he's only projecting men.

Q He was projecting from a population that included men and women using the death rates for men, correct?

A It's very clear when I pointed it out in my deposition the two or three places where he explicitly says he's projecting men and, in fact, when he compares his own curve to SEER data, he compares it to SEER males. So it's very clear to me that he's projecting men.

Q But as we both agreed before, there are deaths from mesothelioma in women as well?
A That's correct.
Q Okay, could you explain to the Court the difference between incidents and prevalence?
A Yes and I'm wondering. I have a slide to do that.
Q Well, let me ask in a leading question manner so maybe we could go a little bit faster. Would you agree that incidents is the number of new cases in a -- of disease in a given population?
A In a given time period, yes.
Q In a given time period. And prevalence is the number of people who have the disease when you observe them at some point in time. It's not necessarily a number of new cases. It's a number of people either still alive or people who have died from a disease at some point in time.
A It's more like a cumulative number.
Q Okay, and I take it that you are not claiming that you have any expertise in projecting claims, correct?
A That's correct.
Q And so you don't have any opinion about whether for non malignant disease it is better to use the prevalence of disease in a population as compared to the incidents of disease in a population?
MS. HARDING: I'm just going to object to form of non

malignant disease.

THE COURT: I can't hear you.

MS. HARDING: I'm sorry, Your Honor. I'm going to object to form with respect to non malignant disease in terms of what Mr. Finch is talking about.

Q Okay, let me rephrase that. You don't have any opinion that when someone is projecting the numbers of non malignant claims, whether one should be looking at prevalence or incidents?

A When one is trying to predict new cases of disease, one should use incidents.

Q But the question was not new cases of disease. The question was new lawsuits. You don't have an opinion --

A I don't have an opinion about predicting new lawsuits, period.

Q Okay, so you don't have an opinion when you're predicting -- when one is set to the task of predicting new lawsuits whether the proper metric to use for purposes of that prediction is to look at the incidents data for non malignant claims or the prevalence of the disease in the population?

A I don't have an opinion about how to predict claims.

Q And that would include non malignant claims, correct?

A All claims.

Q Okay now, the mortality data that we have shows that for mesothelioma people tend to die within a year or two of

contracting the disease, correct?
A That's correct.
Q And for asbestosis, people generally do not die from that disease, correct?
A Not these days, no.
Q And, in fact, isn't it the case that maybe only three percent of the people who contract asbestosis ever die from it?
A I don't know that for a fact?
Q It's less than one in 20?
A It depends when you're talking about. I mean if you're talking about the turn of the 1900's, almost everybody died from it. So it's a time-dependent statement.
Q We're talking about --
A For example, in the insulator cohort, half the people in the insulator cohort were dead by 65 years of age.
Q But they didn't all die from asbestosis?
A That's true.
Q Okay, when you talked about the insulator cohort, you are referring, I take it, to the population studied by Dr. Nicholson and Dr. Selikoff at the Mount Sinai studies?
A Yes.
MR. FINCH: Okay, could I have ACC FCR 2036?
Q And you testified, I believe, when I was asking you questions on voir dire that you had read what you regarded as the relevant -- you had read a lot of literature about the

incidents and prevalence of asbestos-related disease, correct?
A That's correct.
MR. FINCH: May I approach, Your Honor?
Q This is a publication that I'm sure you came across relating to the predictors of mortality from asbestosis in the North American insulator cohort? You reviewed this paper as part of your work here?
A Yes, I'm familiar with it.
Q Okay, if you could turn to Page 103, Table 2 has data about asbestosis deaths in the population?
A Yes.
Q And that shows that whatever the sum of 25 plus 22 plus 19 are the people that died from asbestosis in this population as of the date measured?
A There are so many studies of this. Let me check. Let me see if I can determine the date.
Q This was the date as of 1991.
A That's correct, okay.
Q Okay, and so as of 1991 about 70 of them have died from asbestosis?
A Many more had died from asbestosis by that time. My recollection is, let's see, 66, 76 -- actually, by '86, 400 and some odd had died from asbestosis.
Q Where is that data presented in this?
A It's not in here. It's in Sideman and Selikoff.

Q Okay, but this is looking at -- actually, this study is dated 1991 but it's looking at how many have died by 1983, correct?
A By 1983 -- I'm saying I know that by 1986 over -- somewheres in the neighborhood of 400, almost 500 had died by 1986 so --
Q Died from all causes or from --
A No, from asbestosis.
Q -- just from asbestosis. Okay. And if you look at the numbers of people with asbestosis, there's well over 1,500 of them with asbestosis, correct, as of the date of this study?
A That's correct.
Q And the mortality rate for asbestosis you would expect to be lower in cohorts that were less heavily exposed than the insulator population, correct?
A That's probably true, yes.
Q Okay, so for the insulators, maybe a third of the people that had asbestosis eventually had died from it, correct?
A I'm not quite sure if that's correct, but it's of that order.
Q Okay, but for populations like sheet metal workers or other types of asbestos-exposed workers, the percentage of people who die from asbestosis as compared to the percentage of people who have asbestosis is much lower than that, right?
A Well, you know, this is a carefully-studied cohort and the

problem when you switch to less carefully-studied cohorts is you get into the problem of who really has asbestosis. And, you know, these numbers are based on careful followup of a cohort.

Q You were shown the sheet metal workers study in your deposition, do you recall that?

A That's correct.

MR. FINCH: Can I have ACC 395?

Q This is a population of sheet metal workers studied by the National Sheet Metal Examination Group?

A Yes.

Q Includes David Michaels and Laura Welch as authors of the study?

A Yes.

Q This is another study where there's been a long time followup of the cohort under examination and they were examined for medical screening purposes?

A Not at all the same. This is a cross sectional study. They invited a number of people. I think 40 percent of them showed up and then many of those were not examined. This is a completely different situation than a carefully-followed cohort.

Q Would you agree with me that the mortality from asbestosis depends on the cohort you're studying, correct?

A The mortality from asbestosis depends on the exposure to

asbestosis -- to asbestos.
Q One of the things that you relied upon is the 2004 American Thoracic Society statement on the diagnosis in an issue management of non malignant diseases related to asbestos?
A That's correct.
MR. FINCH: Can I have that on the screen, 389?
Q You are not a pulmonologist or a clinician, correct?
A That's correct.
Q And you didn't interview the British doctors who made up the group that you studied about what diagnostic practices they followed to diagnose asbestosis, correct?
A That's correct.
Q So you don't know whether they followed American Thoracic Society guidelines or some other guidelines, correct?
A That's correct.
Q And the American Thoracic Society does not require lung function decline in order to diagnose asbestosis, correct?
A Yes.
Q Now, could you turn to Page 702 in this document? You would agree with me that there are non malignant diseases caused by exposure to asbestos in addition to asbestosis, correct?
A Yes.
Q And the RAND data that you looked at didn't divide the 300,000 plus claims for disease, non malignant disease into

asbestosis or pleural disease or anything else? They just called them non malignant claims, correct?

A The RAND data did not. I did that by applying the Grace historical claims that 81 percent figure for asbestosis to the RAND data.

Q Okay, you didn't review any of the Grace historical claimants' medical records to see whether they had asbestosis or pleural plax, for example, correct?

A No, but if they said they had asbestosis and the claim was settled for that, I took that to be asbestosis.

Q Well, you didn't review any of the complaints to see whether they said asbestosis or just non malignant disease, correct?

A Correct.

Q You didn't talk to the Grace claims in putters to know whether they typed in asbestosis for insurance purposes versus non malignant disease versus pleural plax? You don't know what kind of criteria for how they typed in the disease?

A These are claims that were settled and they were settled for asbestosis. I don't think it's a matter of entering the data. They were settled as asbestosis, weren't they?

Q You don't have any independent knowledge of that fact, do you?

A No.

Q Okay now, the 2004 American Thoracic Society -- would you

also agree with me that in an asbestos-exposed cohort, some percentage of population will contract asbestosis, probably a larger percent of the population will contract pleural plax and then a much smaller percentage will contract mesothelioma or lung cancer?

A Well again, that all depends on the dose, how well that works out and where you are in time, but I will agree that the people exposed to asbestosis can get pleural plax asbestosis and mesothelioma.

Q You would agree that people exposed to asbestos could get pleural plax --

A Did I say that again?

Q -- and asbestosis and mesothelioma?

A Right. I'm sorry.

Q And you would also agree based on -- I mean obviously it depends on the cohort you're studying, the relative percentages between the three, but generally speaking, far more people contract pleural plax than mesothelioma, correct?

A That's probably true.

Q And the ratio between pleural plax and asbestosis depends on the cohort you're studying, correct?

A Probably, and then it probably depends on how they're examined and depends on many things.

Q Okay, at the bottom of Page 702 the American Thoracic Society, the very last line states, "Pleural plax consistent

with asbestos exposure appear in chest films of 2.3 percent of U.S. males, a percentage that has been -- and it skips over two more pages -- remarkably stable, both for the general population in the early 70's and the veterans in the 1990's." Do you see that?

A Yes.

Q 2.3 percent of United States males is over two million people, correct?

A Yes.

Q And that's a picture of pleural plax?

A No, it's like text. If you represent it as that -- are you showing me Figure 13?

Q Figure 12.

A Figure 12.

Q Can you read the caption for Figure 12?

A Gross appearance at autopsy of asbestos-associated pleural plax overlaying the lateral thoracic wall.

Q One final thing, Doctor, before I pass the witness. You would agree with me that the lengthy period for mesothelioma can be as long as 60 years, correct?

A Probably 50.

Q And you've reviewed the expert claim projections from Dr. Peterson in this case, correct?

A Yes.

Q And the numbers of future mesothelioma claims decline

after the year 2007, don't they?

MS. HARDING: Objection again, Your Honor. I think that the witness has already said he hasn't offered any opinions on Dr. Peterson's claims projections.

MR. FINCH: He is offering opinions on the claims projections. He's offering opinions that the numbers of claims that Dr. Peterson projects for non malignant disease are not medically plausible. That's sort of the sum and substance as I understand his --

THE COURT: But you just asked him about meso claims.

MR. FINCH: He creates his non malignant disease by a ratio to mesothelioma.

MS. HARDING: He didn't ever talk about claims in terms of future. He didn't offer no testimony on Dr. Peterson's estimates of future claims. Today in the courtroom he did not.

MR. FINCH: Okay, with that, I'll pass the witness.

THE COURT: Just a second please. Okay, thank you.

MR. ANSBRO: May I proceed, Your Honor?

THE COURT: Yes, sir, thank you.

CROSS EXAMINATION

BY MR. ANSBRO:

Q Good afternoon, Dr. Ory. At your deposition we agreed that you're not familiar with the term severe asbestosis, is that right?

A That's correct.
Q And your analysis in this case does not seek to distinguish cases of so-called severe asbestosis from less severe asbestosis, correct?
A Right, as we discussed in my deposition, asbestosis is asbestosis.
Q And you did not attempt to break out separately an impaired asbestosis versus what's commonly referred to as an unimpaired asbestosis, is that right?
A Not in the GPRD, no.
Q In your report you did not make any distinction between those two?
A That's correct.
Q But correct that you did not make any inquiry to study what are the distinctions in the levels of severity, the medical distinctions?
A Within the GPRD?
Q Yes, sir.
A That's correct.
Q And nowhere else did you attempt to make inquiry about the distinctions between the levels of seriousness of asbestosis?
A Well, subsequent to the deposition you're presenting me with information from the U.K. mesothelioma registry, I looked at that and I looked at the U.K. mesothelioma -- I'm sorry, the U.K. asbestosis compensation registry --

MR. FINCH: Your Honor, I would object to the witness offering testimony that was not in his report.

THE COURT: He was asked what he looked at. He's just answering the question. Overruled. He was asked whether he looked at -- whether he -- I'm sorry, I cannot restate the question. I did not write it down word for word. The first question regarded whether or not he inquired in the GPRD about distinctions in the medical levels of severity regarding asbestosis and he answered no, and whether he then looked at the other data and his answer was -- he began to answer after the deposition he did and he was answering the question. You may continue, Doctor.

Q If you could look please at --

THE COURT: He may continue the answer.

Q Had you completed your answer, Doctor?

A So after the deposition I looked at the U.K. mesothelioma registry which you crossed me with and then I went back and looked at the U.K. asbestosis compensation registry and I learned that the U.K. asbestosis compensation registry requires only a one percent disability to be registered and compensated. So I have now a comparison of the U.K. compensation registry to the ball U.K. mesotheliomas which would be -- people have at least one percent disability so I have a ratio there, as well as the ratio I have from the GPRD which makes no mention of severity as we've agreed.

Q The GPRD information is input by physicians in the United Kingdom, correct?
A That's correct.
Q Are they -- have you done an examination as to what criteria they used before they determined whether something was diagnosed and labeled as asbestosis put into their reports?
A No, again, this is like the answer I gave about, you know, how is breast cancer diagnosed in the United States and the study I did of breast cancer. I have to accept the treating physician's diagnosis of breast cancer there, and in the U.K. I have to accept the treating physician's diagnosis of asbestosis.
Q To be clear, you don't know on what basis or what criteria or what scales the United Kingdom may look to or not look to before they make a diagnosis of asbestosis?
A That's correct.
Q And with respect to the compensation values that you just mentioned, is it correct to say that the physicians who input diagnoses of asbestosis into the GPRD, that is uninfluenced by these compensation tables to which you're referring?
A I'm sorry, ask the question again?
Q The compensation tables that you're talking about with respect to mesothelioma and asbestosis, does that have any impact insofar as you're aware as to how physicians diagnose asbestosis?

A No, I think it's the other way around. I think that they're required to report mesothelioma deaths in asbestosis cases to the registries.

Q There's no a connection between those two, however?

A That's the best answer I can give you.

Q Turn to what's been previously marked as ACC FCR Exhibit 561. This is your report. I believe you have it up there, Doctor. I'd ask you to turn to Table Four Nine. Excuse me, I pointed you to the wrong --

A You're talking about my rebuttal report?

Q We'll get to that in just a moment. I misspoke. We want to go now to Exhibit ACC FCR 462.

A Which is?

Q Which is the September 25th report on Grace's expert Thomas Florence.

A Actually, turn to Table --

MS. HARDING: Objection, Your Honor. I think that counsel should ask Dr. Ory if he's reviewed --

MR. ANSBRO: I will do that.

MS. HARDING: -- it, presented it and offered opinions on it.

MR. ANSBRO: (Indiscernible) those foundational questions.

Q Have you read Dr. Florence's September 25th report before today?

A No.
Q Had you read his earlier report of June 18?
A I'm not sure. I may have read one report of his. I'm not sure which one it would have been.
Q It's fair to say then you're not that familiar with it?
A That's true.
Q Let me ask you to turn please to Page 14, Table Four Nine.
MS. HARDING: Your Honor, if he hasn't reviewed it, I don't understand what the questioning would be about.
THE COURT: We'll find out.
Q You see at Table Four Nine, Doctor, there's a breakout between these three categories of asbestosis, the first being severe, the next one described as asbestosis and the last unimpaired?
A Yes, I see that.
Q I think I know what the answer to this question is going to be, but do you have any understanding as to why those three categories are broken out separately --
A I do not.
Q -- by Grace's expert?
A I do not.
Q With respect to the distinction between these three types of diseases, am I correct in understanding that you're not saying that any of these categories of asbestosis is by definition medically implausible, is that correct?

MS. HARDING: I'm just going to object again, Your Honor, with respect to him asking about a statement in Dr. Florence's report with respect those categories of diseases when he hasn't had any input in the definition there and he said he hadn't seen this particular report. So I don't have an objection to him talking to him about the categories of the severity of disease but I don't understand the distinction.

THE COURT: So far this witness has not articulated that he agrees that there are categories of this disease so I don't think you've got foundation for the question.

Q Doctor, you see that the Grace's expert report lays these three out? Aside from this expert's report, are you familiar with, in the literature, that it is commonly broken out by severe asbestosis and asbestosis and unimpaired asbestosis?

A From the standpoint of the epidemiologic analysis that I did, I accepted the diagnosis of asbestosis as it was written. It's sort of -- and as I told you in the deposition, the ICD codes for asbestosis only recognize one asbestosis. It's 501 in ICD Nine. There's not 501.1, .2, .3 that says anything else. So as an epidemiologist studying asbestosis, I'm taking the physician's diagnosis. It's coded with a single code so it's sort of -- I hate to use a legal word, but it's sort of moot to me whether there are or are not categorizations because I don't see them in the data that I analyze.

Q Have you seen them generally in the literature and

background information that you've reviewed in connection with this case?

A I have seen asbestosis broken down into different categories, yes.

Q Those three categories often include, and sometimes more, but at a minimum severe and then asbestosis and unimpaired asbestosis, yes?

A Probably.

Q Of the descriptions, and broken down in those categories, of all of those the three types of diseases that I've just listed, they can be medically plausible, do you agree with that?

A I just feel like we're talking at angles here. We talked earlier this morning about to me what medically plausible meant. It meant that someone was diagnosed by a physician using proper methods to have asbestosis whether that -- and I'm saying that the GPRD physicians made the diagnosis of asbestosis and I accept it that way.

Q You would agree with me then that aside from the overall definition that you're using, am I correct in understanding that to the extent that those diagnoses embrace categories such as these, you're not saying that those are medically implausible?

MS. HARDING: It's confusing, Your Honor. I don't understand.

THE COURT: I apologize, if you could restate the question, I think that would be helpful.

MR. ANSBRO: I'll withdraw the question, Your Honor.

Q You can set that aside, Doctor. With respect to the one to one ratio that you derive as between mesothelioma and asbestosis, is it true that no researcher or epidemiologist before you has sought to establish that ratio, is that right?

A That's probably correct although I noticed in reviewing papers I saw Alec Walker did attempt to do such a thing but he did it -- it wasn't an incidents ratio exactly the way I did. It was more of a prevalence.

Q Yours is the first that you're aware of?

A Doing incidents, yes.

Q Your work in this case has not been peer reviewed, correct?

A That's correct. Let me rephrase that. If what you're talking about is the ratio, the one to one ratio, that's not been peer reviewed. But as we talked in my deposition, I believe all the methods that I've used are standard methods.

Q Well, you refer in your deposition to the Nicholson epidemiology analysis?

A Yes.

Q My question is with respect to drawing the one to one ratio as you have done it, drawing upon United Kingdom data and then making a comparison with United States data, that is an

exercise that has not been done before, correct?
A Drawing the one to one asbestosis to mesothelioma ratio has not been done before. But as I stated in my deposition, Nicholson's, and as I stated earlier here, Nicholson's entire method, the entire projection, that rather accurate projection that he's made is totally based on ratios.
Q The answer to my question is correct, right? It's not been done before, the one to one ratio that you have derived here?
A The one to one ratio has not been done.
Q And your work has not been peer reviewed?
A Insofar as it relates to the one to one, yes, that's correct.
Q Now, am I correct in understanding that some patients have both of these diseases, mesothelioma and asbestosis?
A That's correct.
Q And I believe you testified at your deposition that you weren't sure what percentage overall shared both those diseases?
A That's correct.
Q Did you make an effort -- you made no effort to identify that information before you did your report, correct?
A That's not correct. I told you that I did a sample and determined that it would be in the low single digits based on my sample.

Q You excluded that sample from your analysis?
A I did not.
Q Made the allocation?
A No. Can I answer the question more fully?
Q I'll tell you what, I'm going to -- in two topics from now it'll come up again, we'll have an opportunity to talk about that.
A Okay.
MS. HARDING: Your Honor, if the witness would like to answer the question, I think he should be permitted.
THE COURT: It's coming up later. That's fine.
MS. HARDING: That's fine, okay.
MR. ANSBRO: Let's see Exhibit ACC FCR 1071 please.
Q Exhibit ACC FCR 1071 is an article, Ultrastructural Pathology is the publication. This is an article lead authored by Victor L. Roggli. Title of the Article is, "Malignant Mesothelioma and Occupational Exposure to Asbestos, a Clinical Pathological Correlation of 1,445 Cases." Have you seen this article before, Doctor?
A I have not.
Q I ask you to turn please -- first, before we do that, you're aware that in the literature there is a wide range of ratios of asbestosis to mesothelioma in the literature?
THE COURT: I'm sorry, I didn't hear you. Would you restate that please?

Q In the literature, generally are you aware that there are descriptions of wide ranges of the ratios as between asbestosis and mesothelioma depending on job category, for example?
A Oh, I would say it's much more dependent on -- the answer is yes, and it's much more dependent on how early in the epidemic the study was done because of the nature of the timing of asbestosis to mesothelioma. If you have a heavy dose, you're going to get asbestosis early and you may die before you even have a chance to express mesothelioma. So, for example, I looked at the three publications ten years apart of the insulator cohort and in the first cohort the ratio of asbestosis to mesothelioma is 30 to 1. In the next two it's basically one to one. So in 1966 it was 30 to 1; in '76 it was one to one, and in '86 it was one to one.

And again, you have to be very careful about distinguishing incidents and prevalence here as to whether we're talking about an incident ratio or a prevalence ratio.
Q I direct your attention to Page 55 of the abstract. The upper right hand corner tells us about what the study addresses. Third line down from the top sentence beginning, "This study." See that? The introduction reads, "This study reports findings in 1,445 cases of mesothelioma with known exposure, 268 of these also had fiber burden analysis. The 1,445 cases of mesothelioma were subclassified into 23 predominate occupational or exposure categories." Do you see

that, Doctor?
A Yes.
Q If I could ask you to turn to Page 59?
A Without reading this study and understanding his methods, it's going to be very hard for me to comment on it.
Q I won't ask you necessarily to comment on it, Doctor, just to -- let's look at some of the information in here and ask you whether or not you considered it in the course of deriving your ratio. At Table 6 on the far right-hand corner we see ratios among the various industries and occupations of asbestosis to mesothelioma. Do you see that?
A I'm sorry. What are we looking at?
Q Table 6 --
A Uh-huh.
Q -- Page 59.
A Uh-huh. Yes.
Q Right-hand column.
A Yes.
Q As it goes down the right side it shows a variety of ratios depending on the industry we're in or the occupation. Now, the ratios are as between asbestosis and mesothelioma.
A I see what you're pointing to.
Q We see a broad range there. Correct, Doctor? For example, the insulators in this study, the ratio of both those diseases is 58 percent.

A I mean I really can't -- I can't even understand the footnote that describes asbestosis C. I really don't know what I'm looking at here, and I have read a number of studies by Dr. Rogli. I find them very difficult to understand, and without having adequate time to read and study this, I can't comment on it.

Q Let me refer you quickly then to the top of -- or to Page 60, if we could? Lower one quarter of the page, the sentence beginning, "Logistic," on the left side.

THE COURT: You need to stay closer to the microphone. We can't pick you up.

Q I just show you this one sentence, Doctor. "Logistic regression analysis demonstrated that although the category of exposure was significantly associated with asbestos -- asbestosis, P less than .0001, close paren, there was no pattern of one category or another that could be identified as having either a high or a low prevalence of asbestosis. Do you see that?

A Yes.

Q Do you agree that that means the ratio of asbestosis to mesothelioma varies greatly depending on occupational category of exposure?

A Well, first of all, the word prevalence is in there, and I've told you I've done an incidence study. And the second thing is I would like to just read the first sentence of the

materials and methods. It says, "The consultation files of one of the authors, V.L.R., were reviewed for all cases of mesothelioma." And this is simply -- from an epidemiologic point of view, this is a mishmash.

It's just a -- no, that's not an epidemiologic words, but it's just a collection of cases. We don't know where they come from. We don't know anything about them. It's not the kind of information from which I would be comfortable drawing conclusions, probably even if I've read the paper, but having not read the paper, I am just -- I'm willing to draw any conclusions.

Q But would you agree with me that this paper addresses people who have the disease? Yes?

A I don't know what this paper addresses --

Q All right.

A -- because I haven't read it.

Q Fair enough. Now, I want to turn back to one of the slides that was shown to you earlier by Grace's counsel. It's Number 2037.

(Pause)

MR. ANSBRO: It's a Grace slide, yes.

THE COURT: Could we get Grace to put the slide up? Two zero --

MR. ANSBRO: I'll put it on the ELMO, Your Honor.

THE COURT: Oh, on the ELMO?

MR. ANSBRO: It's 2037.

(Pause)

Q Doctor, this is the table that shows the samples that you reviewed, correct, of the UK data?

A I'm sorry. This is the table in which I applied the ratio of asbestosis to mesothelioma -- to the mesothelioma cases in the U.S. and project --

Q Right. My mistake.

A -- asbestosis.

MR. ANSBRO: Actually, Your Honor, let's now look at Grace Slide 2036.

Q This shows the breakout of the global resolution -- the GPRD data into the two categories of the sample that you analyzed. Is that right?

A That's correct.

Q And, Doctor, am I correct that some of the patients that were in your sample set had both diseases?

A That's correct.

Q Now, you've got the two diseases discreetly broken out. Correct?

A Yes.

Q And so to be clear, the patients who had both diseases in the sample are included here, you have categorized them in one disease or another. Correct?

A Subsequent to this line of questioning on the deposition,

I looked into this matter exactly, and, in fact, both are -- there are 28 people who overlap, and they're in both groups.

Q What did you go back to after the deposition to learn that?

A I went back to the GPRD and asked them to run me another data set keeping both diseases on the same record, so if they were present, I could count them.

Q And so have you made that adjustment here?

A If I make an adjustment, it would lower the ratio to .91.

Q I want to talk now just about this exhibit which formed the basis of your analysis. At some point you wanted to know that if someone had both of those two diseases, which would they be more likely to claim in the lawsuit. Correct?

A I mentioned that in the -- yea, in the deposition. Yes.

Q And to get an answer to that question you asked Grace's counsel. Correct?

A Yes.

Q And as I understand your testimony from your deposition, Kirkland and Ellis advised you that in a situation where a patient had both diseases that person would be more likely to claim for mesothelioma.

A Yes.

Q Okay, and on that basis, with respect to this table, were those people who had both diseases, you put them into the mesothelioma category. Correct?

A No, I have just corrected myself. I said subsequent to the deposition I went back and checked. I put them in both categories. Had I only -- I put them in both categories. This -- as it stands here, the 28 people who share the diagnosis show up in both groups.

Q So that when you testified at your deposition that you had, in fact, moved such a person into the mesothelioma category, that was not correct?

A In my deposition I said I wasn't certain. I said that I thought that's what I did. In fact, that's not what I did. I did what I just told you I did.

Q Turn to the Nicholson forecast as it has been adjusted by KPMG in consultation with Dr. Nicholson. That is a update of his 1982 work that runs the projection of mesothelioma claims out to 2049. Do you understand that?

A Which projection? Which KPMG one?

Q The piece authored by Vasquez. Have you seen that?

A I've seen the 1999 one -- 1991 one.

Q You are aware that there has been a subsequent update to the Nicholson '82 work that further projects mesothelioma incidence beyond 2027?

A I'm aware there has been a KPMG update, and I think there have been two, actually.

Q Okay. You're aware that Nicholson was a consultant to at least one of those exercises?

A Yes.
Q You have nevertheless chosen to not use that updated Nicholson work. Is that correct?
A That's correct. I've chosen to go with the one that's published in the scientific literature.
Q Are you saying that the later work by KPMG is not scientific in some way or not reliable?
A No, I said it wasn't -- to use your words, it wasn't published and peer reviewed, so I stuck with Nicholson's '82 projection.

MR. ANSBRO: That's all I have for the moment, Your Honor.

MS. HARDING: Your Honor, can I have about two or three minutes just to gather my materials?

THE COURT: Yes. Let me find out is any -- is there anyone else cross examining?

(No verbal response)

THE COURT: All right. Why don't we take a five-minute recess? I'll think that will help. And then we'll reconvene on redirect.

(Recess)

THE CLERK: Please be seated. Let the court come to order.

THE COURT: Doctor. Ms. Harding.

REDIRECT EXAMINATION

BY MS. HARDING:

Q Doctor, is there any study, any question, anything presented to you today at all that changed your analysis or ultimate conclusion with respect to the exhibits and analysis that we talked about today in your direct examination?

A There were none.

MS. HARDING: Could you show me the first one, please?

THE WITNESS: I said there were none.

MS. HARDING: No. I'm sorry. I was talking to T.J.

T.J.: The first one?

MS. HARDING: The first one admitted.

T.J.: Okay.

MS. HARDING: I'm sorry. I'll give the number, 2036.

BY MS. HARDING:

Q This is your creation of the asbestosis and mesothelioma ratio. Has anything that you were confronted with today changed or altered your analysis or your alternate opinion about the reliability of your ratio?

MR. ANSBRO: Objection. That's been asked and answers.

A No.

THE COURT: Yes, that's sustained. He's asked and answered. We're not going to run through these. That's a waste of everybody's time. He testified quite clearly. I

understood it.

MS. HARDING: Okay.

THE COURT: They've asked. We don't need to do this.

MS. HARDING: Fair enough, Your Honor. I understand.

Q Dr. Ory, with the exception of the article by Dr. Rogli, had you reviewed in detail all of the material -- except for the expert reports that you hadn't seen, had you reviewed the studies that had been presented to you and you were asked questions about?

A Yes.

Q Had you considered the information in those studies in rendering your analysis and the methods that you used and your conclusions?

A Yes, I did.

Q With respect to the study -- I believe it's a case series or a series of case reports from Dr. Rogli, that I can't find -- I'll ask you about that if I can find it.

(Pause)

Q You were asked a number of questions at the beginning of your testimony about the inclusion or exclusion of women in your analysis. Correct?

A That's correct.

Q And you explained that -- as I understand your testimony, you explained that it would not have been appropriate to include women in your analysis, because Dr. Nicholson did not

include women in his analysis. Correct?
A Yes.
Q And Mr. Finch asked you a series of -- asked you a couple times, but there were women in his population. Correct?
A That's correct.
Q Okay, and as I understand, is it -- is what's meant by that that within a workforce at the -- during the time period covered there might have been some women involved in working in areas or occupations where they might have been exposed to asbestos?
A That's correct.
Q Okay. Dr. Nicholson recognized that. Right?
A Absolutely. He discussed it.
Q But when he -- when he conducted his study and derived ratios and risks and all of the things that drive his study --
A Right.
Q -- he used male mortality ratios. Correct?
MR. FINCH: Object to the leading, Your Honor.
THE COURT: That's sustained.
Q Okay. Did Dr. Nicholson use male mortality ratios -- male mortality data?
A Yes.
MR. FINCH: Same objection.
MS. HARDING: Did. I said did -- did he.
THE COURT: That doesn't make it non-leading. That's

sustained.
Q Doctor -- Dr. Ory, what did Dr. Nicholson do that is relevant to the issue of whether you should, in using his forecast, without correcting his entire work do when comparing to mesothelioma incidence data?
A Well, I stated clearly that Dr. Nicholson projected male mesothelioma rates, and not only does he say he did that, but further along in his analysis at one point he compares his -- he compares the data that he had so far to SEER -- and he compared it to SEER male rates, so I'm quite certain that he was projecting men.
Q Just for clarification, Dr. Ory, I'm going to ask you -- I'm just going to show you Page 297 of Dr. Nicholson's paper.
A Right.
Q Is that the part of Dr. Nicholson's study that you're referring to?
A It doesn't look it, but let me --
Q No? Okay.
(Pause)
A Oh, I'm sorry. The second paragraph --
Q Yes, I'm sorry. Yes.
A -- where he says, "The number of mesothelioma is estimated by this procedure as approximately 40 percent greater than those that would've been estimated to occur nationwide using data of the SEER Program for white males during 1978, personal

communication from SEER."
Q So when Dr. Nicholson was comparing his own estimates in his study and some of the work he had already done in it, he used male mortality data to compare it to them from SEER. Correct?
A Absolutely.
Q Now if you had included women in your analysis, how would that have affected your ultimate conclusion?
A I would've had a lower incidence ratio.
Q Thank you, Dr. Ory. The next question I have is with respect to a study you were shown by Markowitz Morabia.
A Yes.
Q This study here. I'll show you. Do you know which one I'm referring to?
A Yes.
Q Okay. You've seen that study before. Correct?
A Yes.
Q Did this study involve a co -- well, let me see this. What were the death intervals that were involved in this study?
MR. FINCH: Objection. Lack of foundation.
THE COURT: He said he's read the study.
MR. FINCH: Is this the Rogli study?
MS. HARDING: No.
MR. FINCH: Markowitz study. Oh.
THE COURT: No, it's Markowitz.

A It looks like there was a ten-year followup study.
Q Okay, and what does that mean to you in connection or what relevance does that have with respect to whether or not the information in this study is relevant to the work that you did in this case?
A Well, I was very interested in the insulated cohort, and that's why I looked at all three papers that -- four actually if you include this one. But there was done every ten years, and I looked -- maybe there's one after that. I hadn't found it. But I was very curious about how the insulated cohort changed over time.
Q Just because it was so helpful to me when you showed it to me, could you show on the board what you saw when you looked at the insulated cohort over time?
A If I remember.
Q There's a pen right up there.
A Yes.
Q You have to -- well, you have to write it first maybe?
MR. FINCH: Objection, Your Honor. This wasn't in Dr. Ory's report.
THE COURT: This is redirect. This is fair. He's asked -- you asked -- somebody asked him about the Markowitz study and certain parts of the mortality tables and also about the insulator studies about which he testified on cross examination and the three times that he used them in '76, '86,

and '66, and now he's following up. This is proper redirect.

MR. FINCH: Even though it's new --

MS. HARDING: He didn't rely upon it in forming his own analysis, but he knows about it, and he was asked questions about it, and he's explaining why he -- why -- what he found in it that he thought was important.

MR. FINCH: Very well.

THE COURT: Go ahead, sir.

A Well, it's what I said in my testimony. That in 1966 I believe there were 339 cases of asbestosis and ten cases of mesothelioma. In the '76 followup -- and these numbers are approximate -- there are 170 cases of asbestosis and mesothelioma, and by '86 there were something like 480 -- about 460 cases of asbestosis and about 480 mesotheliomas. So what my point was on that was if you looked here, you would've seen an asbestosis to mesothelioma ratio of 30 to 1, but it's these two are one to one as the cohort went on, and the -- I imagine the people who were very ill from asbestosis died, and that the mesothelioma cases -- well, more of the -- look at the rise in the meso -- strike the first comment.

The real difference is look at the rise in the meso cases. There's nothing biologic about the one-to-one ratio. It just happens to depend on where you are in time. I mean that -- that's not well said. The one-to-one ratio is based on the biology that asbestos causes both asbestosis and

mesothelioma, but what that ration is is depend -- is very time dependent on where you are in the asbestosis epidemic.

Q Is that -- you explained the distinction early on about why you looked for an incident approach as opposed to a prevalence approach. Is that why?

A That's one of the reasons, yes.

Q You were asked some questions about the low -- lower-exposed group of workers in the Nicholson study. Do you recall those -- that line of questioning?

A Yes.

Q I'd like to --

MS. HARDING: May I approach the witness, Your Honor?

THE COURT: Yes.

MS. HARDING: Thank you.

(Pause)

MS. HARDING: I'll wait until I have copies, Your Honor.

THE COURT: What's the exhibit number?

MS. HARDING: It's the ACC FCR's 1097 exhibit.

THE COURT: All right. Thank you.

(Pause)

THE COURT: That was the witness' copy.

BY MS. HARDING:

Q Have you seen this study before, Dr. Ory?

A Oh, yes.

Q What is it?
A This is a presentation of an early version -- earlier version of Nicholson's model to Branberry (phonetic) conference. I think it was presented a year earlier.
Q If you could turn to Page 106, please?
A Yes.
THE COURT: Could we get it up on the screen?
MS. HARDING: I'm looking for that page, Your Honor. I'm sorry. Oh, there we go.
THE COURT: And may I have a copy?
(Pause)
THE COURT: Thank you.
Q Dr. Ory, what is the figure on Page 106, if you know?
A Figure 7 is the estimated and projected numbers of mesothelioma per year from 1940 through 1999 from the occupational asbestos exposure.
Q Okay, and what did this study tell you about the inclusion of the lower -- if anything, about the inclusion of the lower dose category of exposed people in the Nicholson report and his estimations on mesothelioma?
A Well, what's -- this is one of the most curious things in all the work that I did that I noticed. If you read Conclusion 1 here and -- which accurately reflects what the paper says, it says from 1940 to 1979 13 million individuals had significant potential asbestos exposure to work, and what's really striking

is a similar figure appears in the Nicholson '82 paper, which you can put up. And it's the identical figure in spite of the fact that Nicholson has doubled his population -- his exposed population to 27 million. And do you want to show -- could you show that?

MS. HARDING: I'm looking for it. Sorry. I apologize. I thought I had it with me.

(Pause)

THE WITNESS: You could just put the Nicholson slide upon the ELMO from --

MS. HARDING: I'm looking for that, Dr. Ory.

Q Do you recall what page it's on?

A It's towards the end.

UNIDENTIFIED SPEAKER: Page 298.

MS. HARDING: No, that's not it.

THE WITNESS: No. No.

MS. HARDING: That's not it.

UNIDENTIFIED SPEAKER: Two ninety-eight.

MS. HARDING: Thank you.

THE WITNESS: Right.

(Pause)

Q Is that the same figure? Is that the figure you're referring to? This is from Nicholson's report --

A Right.

Q -- paper now.

A Right.

THE COURT: So you're looking at the ACC Exhibit 1 now, Page 298? And --

MS. HARDING: Yes, Your Honor.

THE COURT: All right. Thank you.

MS. HARDING: Thank you.

A And what's striking to me is this figure looks remarkably similar to the figure presented the year before based on 13 million people. This figure -- this paper that this figure appears in is based on 27 million people, and yet the curve doesn't seem to change. So it would suggest to me that the 13 million people that were added didn't add very much in the way of risk. That it was the original 13 million people that carried the risk.

Q One last series of questions, Dr. Ory, just to make sure the record's clear with respect to the issue of the data that you used in -- with respect to the mesothelioma incidence in the United States. You were asked a series of questions about the SEER data with respect to SEER 9 and SEER 17. Is that right?

A Nine, 13, and 17.

Q Nine, 13, and 17. What's the -- could you maybe go to the board and explain the distinction in the progression of the SEER database?

A SEER 9, which means it had 9 centers involved, it's just

-- started in '73, and it went until '89 I think. I might be wrong on that. And it covered about 9 or so -- 9 and 10 percent of the population. SEER 13 added more centers, and it ran from -- well, actually, it runs -- they still produce the data, so it runs from '73 on. SEER 13, the additional centers were added around 1991 or 2. So let's say '91, and that covered about 14 percent of the U.S. population.

SEER 17 added more centers, and it -- those centers were added in 2000, and it covers about 25 percent of the U.S. population. At about the same time that was going on SEER and CDC got together and they now publish something called the USCS, the United States Cancer Surveillance, which now covers 98 percent of the U.S. population, and this runs from 1999. The latest date is from 2004.

So the USCS includes all the SEER centers, plus it goes out and gets the rest of the country. So, you know, as far as I'm concerned, from 1999 on, if SEER was the gold standard, this is now the platinum standard.

Q Thank you, Dr. Ory. And you used the most -- the data that had the most information in it -- the USCS data included with the relevant SEER data in doing your analysis in this case. Correct?

A Whenever possible from 1999 on, yes. Whenever possible from 1999 on.

Q I'm sorry. I want to -- I do want to go back to the

Branberry figure one more time -- the Branberry Nicholson. This is the Nicholson figure. Could you explain the significance of that discovery -- you know, that finding that when Dr. Nicholson added that many million workers who were on the lower exposed end with respect to his projections of mesothelioma?

A Well --

MR. FINCH: Objection. Asked and answered.

THE COURT: Well, it may be, but frankly, I'd like to hear it anyway, so I'm going to overrule the objection for my edification. Go head.

A If your study -- Nicholson's method says these 13 million people carry all the risk, and he comes up with a curve that seems to be quite the same as the curve we're all used to seeing now that has 27 million people in it. So I draw the conclusion that the 13 million people that were added added a vanishingly small amount of risk. They must not have been very exposed.

Q And, Dr. Ory, could you --

MS. HARDING: I'm sorry. T.J. could you put up the last slide of the direct examination, please?

THE COURT: Excuse me. May I ask? I think what I'm confused about about this testimony is the 13 or 14 million people who were added are all the lower exposed people in the Nicholson study?

THE WITNESS: He doesn't say that explicitly. I'm drawing that conclusion, because how else can you add people and not change the shape of the curve?

THE COURT: All right. Thank you.

MS. HARDING: And perhaps this might help, Your Honor, as well.

Q Dr. Nicholson's estimates were based on risks relative to insulators, and the -- for different categories of people exposed, and the risk was lower as you went -- lower associated with certain groups of people and higher with respect to other groups of people. Correct?

MR. FINCH: Objection. Leading.

THE COURT: I -- this is a foundation question.

MS. HARDING: Thank you, Your Honor.

A The highest -- Nicholson -- as I said earlier, everything was a ratio to Nicholson, and so he gave the risk and the insulators to be one, and as people's exposure got lower, he gave it as a fraction of that. So like the lowest group got one percent of the risk of the insulators.

Q And as I understand it, I think is it fair to say that he could not -- in other words, it's not possible in his model to add people with lower -- with higher exposures in his model and not get significantly more mesotheliomas. Is that fair?

A That would be my understanding.

MS. HARDING: Did you -- do you have that last slide

T.J.? Thank you.

Q I want to ask you, Dr. Ory, is the conclusion that you drew from seeing those two curves from the earlier Nicholson work in the Branberry report and the later Nicholson report, is that supported or contradicted by the evidence that you -- that we admitted in 2050?

A Well, I think it's supported. I mean this curve more than any other exhibit that I've put up says to me that if you take away asbestos exposure, you take away mesothelioma, and it tells me it's been taken away in the young people. Their risks are plummeting. And I guess the other really important thing about this slide to me is it tells me there's no, whatever the parlance is these days, no second wave or third wave, fourth wave, because if there was a wave of people with enough exposure to asbestos to be causing mesothelioma, we'd be seeing it in the 20 to 54 year olds like we did in 1973 from the slide that I showed.

MS. HARDING: Thank you, Dr. Ory. No further questions.

THE COURT: Any recross?

MR. FINCH: No, Your Honor.

MR. ANSBRO: Nothing further, Your Honor.

THE COURT: You're excused, Doctor. Thank you. Mr. Bernick.

MR. BERNICK: Let's take the next witness?

THE COURT: Yes. Well, Mr. Bernick, I'm sorry. Do you need a recess to get ready?

MR. BERNICK: No, I --

THE COURT: If you do, that's fine.

MR. BERNICK: If you'll excuse me one moment.

THE COURT: No. Okay. That's fine.

MR. BERNICK: I don't know -- I'm not sure of the Court's -- yea, well, let's start out with it. Dr. Rodricks is going to take the stand.

(Pause)

MR. BERNICK: Due to the insecurity of my height, Your Honor, I would like to look over the podium if you'll indulge me.

THE COURT: We need to get the witness sworn. You need to call him, please.

MR. BERNICK: We call Dr. Rodricks to the stand.

THE CLERK: Would your raise your right hand?

DR. JOSEPH RODRICKS, DEBTOR'S WITNESS, SWORN

THE CLERK: Please be seated.

MR. BERNICK: Good afternoon, Dr. Rodricks.

THE WITNESS: Hello.

VOIR DIRE

BY MR. BERNICK:

Q Could you just tell us, in order to acquaint the Court with what you're here about this afternoon, what it is that

you've come here to talk with us about?
A I've come to talk about the signs of risk assessment, its application in the evaluation of causation of disease, and its application in some regulatory public health context as well.
Q In a few words -- and I know we'll have an opportunity to go through more -- could you tell the Court what risk assessment is?
A Risk assessment is a rigorous scientific framework use to evaluate research information, other complex scientific information, to evaluate the likelihood that under certain conditions people will be harmed by exposure to toxic agents.
Q Do you have a background in risk assessment, Dr. Rodricks?
A I do.
Q Okay. Let's begin with your education background.
MR. BERNICK: And I'd like to show the Court Slide GG-2002.
Q Could you -- making reference to that demonstrative, could you just go through briefly what you educational background is?
A Briefly, I began life as a chemist out of MIT in 1960. I moved on to study at the University of Maryland. I moved into biochemistry for a PhD. I did post-doctoral work in biochemistry at the University of California, Berkeley as well.
Q Okay. Let's talk about your professional experience.
MR. BERNICK: And if we could bring up GG-2003.

Q Again, in your own words looking to the slide, give the Court an overview of your own professional experience.
A Yes. I spent 15 years -- my first position after finishing graduate work was a -- as a scientist at the U.S. Food and Drug Administration for 15 years specializing in the analysis of risks from substances regulated by FDA. I built on that basic scientific background, and during this time period was a period when these new tools of risk assessment were beginning to be used, and I was there pretty early in that process. So I worked on a whole wide range of products. And my last four years at FDA -- three and a half years at FDA I was in the Office of the Commissioner of FDA as an Associate Commissioner for what we called health affairs at the agency.
Q Go ahead.
A Well, I began, as I got into the risk assessment field, working from the sciences of toxicology and epidemiology as the basic sciences. I got into the risk assessment field, and beginning in the mid-70s -- I guess 1977 -- I was asked to serve on a Committee of the National Academy of Sciences. The National Academy is a knowing governmental entity that does expert consultation for the government on all kinds of matters, and I have since served on more than 20 expert committees of the Academy in that period looking at a very wide range of issues related to hazardous substances and the risks they pose to health.

Q Okay. Let's talk about Environ.
A Environ's a firm I'm now with. I've been there since 1982. We're a 25-year-old consulting firm with offices around the globe doing a very wide range of scientific consulting again on matters of risk to health from substances in the environment and the workplace, in consumer products. It's quite varied in context. Some of it related to regulation of those products. Some of it related to issues of disease causation.
Q Okay, and finally Johns Hopkins.
A I was -- in the mid-1990s I was asked to join the faculty as a visiting professor at the school in Baltimore, and I teach there a course in quantitative risk assessment methods. It is called public health.
Q Let's turn to some of your publications. I want to turn to GG-2004. What's the Red Book?
A This is a shorthand term for a book which has a red cover, but it's quite a prominent work in the field of risk assessment. There was a lot of turmoil in the science of risk assessment during the 1970s. Congress asked for a National Academy of Science study in the early eighties of the whole process by which we look at risks to health and the scientific tools for doing that. The Red Book -- I served on this committee. I reproduced a volume in 1983 from the National Academy which has set the stage for almost everything that has

followed by way of risk assessment in regulatory agencies and many other institutions. The framework for risk assessment that we now use was originally formulated there. So this is quite similar work. I was very both fortunate and pleased to be on that committee.

Q Have you also done some writing in work in connection with risk assessment or its applications in toxic tort litigation?

A I have. I began in the eighties when I first got introduced to this issue. Most of my early work with risk assessment was in the regulatory context, but increasingly during the eighties issues of tort arose where there had to be some scientific evaluation. So I got interested in this and began writing and thinking about the problem at that time. So I have a couple of early papers from the eighties that I think I list there. Yes, on the bottom.

Q Okay.

A And then I -- my thinking had advanced quite a ways by 1998, and that paper in '98 was I think a -- I hope a substantial contribution to this field, but I -- it was a look at the state of the science and its interaction with some of the legal standards at that time.

Q Continuing on to GG-2005, what do these publications relate to?

A This might be a bit redundant. The same topics basically. I have a book on the subject of risk assessment in general, the

one at the top, and I just recently -- in the second edition I introduced a whole new chapter on the issue of causation and tort. It had not been in the first edition back in the early ninties. And this Journal of Law and Policy article evolved from a seminar I gave at Brooklyn Law School -- seminar for judges. This is a bit redundant, but it's more on this topic, which I've spent quite a bit of time looking at.

Q Have you had any involvement in recent years in connection with activities of the Federal Judicial Center?

A I have. I gave a talk to a gathering at Georgetown University last summer on issues of the use of toxicology and related information and analysis of causation. I met one of the editors of that journal there, and he invited me to sit on an advisory panel. There's a third edition coming out I guess. I'm not sure when it'll come out. We're just beginning to look at a third edition of the manual, so I'm advisory. I don't think I'm asked to write anything but to advise on the content of it, yes.

Q Have you been asked, Dr. Rodricks, to testify today regarding the specifics of risk assessment for asbestos in particular?

A Not for asbestos in particular, no. I'm talking about the general methods for evaluating causation using that framework.

MR. BERNICK: Okay. Your Honor, we would offer Dr. Rodricks as an expert in risk assessment.

THE COURT: Any objection? Any voir dire?

MR. MULLADY: No, Your Honor, not from the future claimants.

MR. FINCH: No, Your Honor, as long as it's limited to risk assessment generally and not risk assessment in the asbestos context.

THE COURT: He's --

MR. BERNICK: I think all the questions will be posed with respect to risk assessment generally, and we will later be building on that in our case on what he's indicated. We want to establish the (indiscernible) cases (indiscernible).

THE COURT: Dr. Rodricks, without objection, may offer an expert opinion in the area of risk assessment.

DIRECT EXAMINATION

BY MR. BERNICK:

Q Let's talk for -- at the outset, Dr. Rodricks, about this. Does risk assessment deal with causation of disease by potentially toxic agents?

A That's one of its applications, yes.

Q Are you familiar in general terms with the basic evolution of the criteria for causation by toxic agents?

A The general evolution. Yes, I am.

Q Okay. Do you have a --

MR. BERNICK: We have a demonstrative that's been prepared that would assist the Court in walking through that

basic evolution. I would like to show the Court and counsel GG-2006 as a demonstrative.

MR. FINCH: Your Honor, I would object to this demonstrative to the extent that it has anything about the Federal Judicial Center manual on it. This is a witness who didn't write that. That's a legal text. I believe that it -- it's a legal authority no different than a brief for a case. I believe it fades the province of Your Honor for him to be offering any testimony about the Federal Judicial Center manual or to be giving testimony about what should or should not be required in a court of law to establish causation. I think that's a legal opinion. It's not something that's a proper subject for a witness.

MR. BERNICK: You don't mind if I -- that's really not the purpose of the proffer at all.

THE COURT: Well, may I see it, because since I don't know what specifically you're referring to --

MR. BERNICK: All it is at this point is an icon. It says, "Federal Judicial Center Manual."

THE COURT: Right. I will take your objection under advisement when the witness explains what it's doing there, Mr. Finch, because until I hear it, I'm not sure what the purpose of this is, since it's demonstrative. So I will give you a ruling when I understand the nature of the objection in the context of this document, because just seeing an icon there

does not necessarily tell me that it is an improper use of an icon. So I will rule on the objection when I hear what the icon's purpose is.

MR. BERNICK: Thank you.

BY MR. BERNICK:

Q If you could begin at the left-hand side of the chart, and I want to, first of all, focus on causation criteria where it refers to Koch's Postulates. In the period before 1964, were there postulates called Koch's postulates that related to causation?

A Yes, these were the earliest attempts by scientist physicians to set forth some criteria to understand -- lined to understand when you apply them, aspects of disease causation. They actually emerged in the late 19th century.

Q Okay. It says infectious disease model. What does that mean?

A Well, they were based on what was then, when they were developed, the key concerns about disease causation, and that were -- those were related to infectious agents. Tuberculosis was one of the major issues at that time. And the model was based on the notion that one infectious causes one disease, and it had some very simple criteria for establishing when you were sure you could establish causation between an agent and a particular infectious disease. So that was a model which was well received and stood for those classes of diseases -- acute

infectious diseases. They stood a long time.
Q Okay. At this point in time, that's prior to 1964 and going back into the thirties and forties, what was the status of epidemiological review or research regarding toxic agents?
A Well, there was a lot of interest in the subject of toxic agents often focused on occupations or medicines where there were reports of adverse events, but most of those were not really studies. They were reports by physicians. We call them case reports where they have an individual with a disease, and they think they can sort of establish what might have caused it, or they may have a series of diseases. They're not controlled studies, but they were the earliest attempts to understand relationships between exposure and disease.
Q As we go to the later period of time coming up, fifties and 1960s, what, if anything, happened regarding the strength of the observational studies?
A They increased. Some very inventive scientists in England and in this country focusing primarily on smoking in the 1950s/early 1960s. Also radiation. Radiation, of course, was a major issue during that same period, and some very inventive scientists thought of new ways to observe populations that have exposure, and you cannot create the exposure intentionally, but you can observe where it's occurring and try to set up something like a controlled study. They're never perfectly controlled. You can't do that. So these studies began to

emerge in the 1950s and sort of really advanced the field.
Q Okay. Now did a time come when as a result of the increased strength of sophistication of this epidemiological -- did the time come when that had an impact on the scientific community's assessment of when causation could be or how causation could be proven?
A Yes, it had a very strong impact. The smoking studies in particular. I'm sorry.
Q What was that impact, and when did it occur?
A Well, there was a lot of controversy over those early smoking studies, and whether a -- they established what are called associations between smoking and certain diseases. And, actually, some of the early studies showed several diseases. And so one of the issues that raised was whether the old idea of the one agent/one disease idea held up anymore. And a lot of people said this is contrary to Koch's Postulates. And there are other issues, too. These were now mostly chronic diseases. Some of them have other causes.

Remember with infectious there are no other causes of tuberculosis except the agent, but all of these diseases that emerge with smoking had other causes. So that -- a group got together under the surgeon general of the U.S. at that time saying what do we make of all this kind of evidence, which looks good, but we also know it's limited? So they developed and published in 1964 -- is a seminal. That's why I put it

there -- the so-called Bradford Hill criteria that epidemiologists still used today to evaluate scientific epidemiology information to see whether it moves from associations and studies, so real causation -- disease causation.

Q Does this chart or this demonstrative then go into, I guess for want of a better phrase, the ripple effect of the endorsement of new criteria for causation?

A I tried to illustrate in the third column, yes.

Q Okay. And I know that once we get to that judicial interface, I'm very controversial here, so let's begin with the easy stuff. First of all, what, if any, effect did the option of the Bradford Hill criteria have on the scope of --

THE CLERK: Can you use the mike?

Q -- on the scope of epidemiological research?

A It has strong effect, because now once these criteria gained wide acceptance, the epidemiologist had to begin thinking about designing studies to give information that could be evaluated using those criteria if you had any hope of establishing causation. So the studies changed. They came up with different protocols for studies, different ways to look at population retrospectively or prospectively, new ways to measure exposure in those populations, and that's still expanding. It's become quite quantitative. It has ways to go, but it's really quite an advanced science now.

Q When focused on regulatory approaches, is this an area in which you now make reference -- is this an area where your own activities had focused after I'll say after the 1960s and going forward to the seventies and eighties that is the impact of epidemiology on regulatory promotions?

A Absolutely. The regulators have a very wide mandate to protect public health in a lot of different contexts, and we knew and regulators knew well that all chemical substances -- I'm focusing on chemicals -- can be hazardous under some conditions, and we also know that they're not hazardous under other conditions, and we needed some good tools -- a good framework to analyze whether under specific conditions the toxic properties would express themselves, how likely it was, and how like -- and then where that likelihood got to be very small. So this risk assessment model evolved during this period, and it's still evolving, but it has now very, very wide use in this sort of context.

Q Okay. All right. The models -- and I -- we'll just focus on this a little bit really as a marker. There's been a lot of discussion already in this trial about models. Are all risk-based models for regulatory purposes -- are they identical? Are they identical in scope with scientific models, or are there differences sometimes between regulatory risk models and scientific risk models?

A Well, they're all done within the same risk assessment

framework, but they're emphasizing different aspects of the science. The causation models tend to focus on -- should focus on the real observed science. Regulators will go beyond the observed science in many cases and introduce assumptions for public health protection. So the same framework, the same data sources apply, but then there are differences in application.

Q More of that in a moment. Today is there or is there not a widely accepted framework for risk assessment within your opinion?

A There is a widely accepted framework for risk assessment, yes, and it is very widely used.

Q Now when we went through the history that you just discussed, we focused on the development of epidemiology and how epidemiology affected causation criteria which in turn had impact on risk modeling. Does epidemiology play a basic role in risk assessment?

A It is one of the fundamentals of risk assessment. There are other aspects of science, but it is a fundamental piece of the risk assessment process.

Q I'm showing you for illustrative purposes GG-2007. Does this set out in very broad terms -- does this set out the elements of the risk assessment framework?

A It does, and to be accurate about it, the framework itself is on the right-hand side of the dotted line. I put some information on the left side of the dotted line that talks

about the sources of information. The questions being posed, if you like, and the analysis -- the evaluation occurs in the steps that I've shown there on the right side of the dotted line.

Q What are the elements of the risk assessment framework itself?

A Well, first of all, the question which is on the -- I gave one example here on the far left. We're looking at in this case a group of individuals. They have a disease. They claim chemical exposure caused it. The assessment framework -- if you want to look at this question and evaluate it, you first look at the underlying science, the epidemiology, even some other sciences as well. You look at exposure as you try to put that all together, and the framework is a way to help you organize and evaluate it.

So the first step under what I call -- those are the terms used by scientists when they do the risk assessment, the hazard identification, the dose response, how strong is the evidence that the chemical causes the disease. That would be the first thing you'd want to look at. In other words, we have claims of disease where there's chemical.

If you found that there's no evidence the chemical can cause the disease under any circumstances, then you might stop your inquiry. But if you begin to find evidence, you want to see how strong it is. Is it convincing? And at the same

time you're also looking at this very, very important question, the second one there called dose response. That is how does the rate of disease or the risk of disease change with dose?

Q Let's focus then in more detail on epidemiology.

MR. BERNICK: And I apologize, Your Honor. Some of this may already be well known to the Court, but I'd like to make a record very, very briefly.

Q Turning to Slide GG-2008, can you run for us through this -- run through this for us briefly as an example that illustrates how epidemiology works?

A Well, it's a part example, but it's exactly what epidemiologists try to do. They look at people who have one kind of exposure to an agent. In this case I've shown smoking. They try to then identify populations that do not have that exposure and see if there are differences in disease rates in the two. That's basically it. I -- in this case I've emphasized that those studies -- individual studies of these differences of disease rates are said to develop an association or not between the exposure and the disease. These studies by themselves individually cannot establish causation, but only whether the disease occurs more commonly in one population than the other. And if it's -- if that association exists, it's called that. The reason these are not association -- not causal in a single study is that these are not perfectly controlled studies. The only way you get causation is with

perfect controls, and observation doesn't allow that. So you have associations.

Q Okay. Now the Bradford Hill criteria that were adopted in 1964/1965, do they help us tell when the body of data is sufficiently strong to be able to say causation?

A That's exactly their purpose, yes.

Q Okay. Showing you GG-2009, are these the Bradford Hill criteria?

A Yes, these are the key criteria that one would look at. You begin by collecting all of the studies together. You wouldn't apply this to a single study. We know the single study would never be enough, so you don't even have to think about that. But once you accumulated a body of evidence, you then begin looking at that body of evidence. This is usually done by expert groups, and you look at things like how strong the association is. You tend to see the same association over and over again or not. Is it clear that the exposure always precedes the disease? Is there what's called a biological gradient -- does the risk -- this is very important, because it is well established in toxicology and epidemiology that the more exposure the greater the risk. So if you don't see increasing risk with increasing exposure or dose, that would reduce the reliability that the -- the likelihood of a causal relationship. So these are applied routinely now to establish causation or not from the associations.

Q We'll now walk through how epidemiological studies read out in terms of results, and for those purposes I want to give you a hypothetical example about epidemiology relating to a drug.

MR. BERNICK: Showing -- let's show the Court GG-2012 for illustrative purposes.

Q Where you have an epidemiological study relating to a drug, what are the two groups from which data is gathered?

A Well, you'd -- this chart references what might be called a clinical trial, which is one kind of very controlled epidemiology study, but you could do this without a clinical trial. But, basically, people taking the drug, people who do not have a drug -- do not have that drug, and you look again for differences in disease rates in the two populations.

Q Okay.

A We refer to that difference as a relative risk. You're looking at the risk of disease in one versus another.

Q Okay. So let's assume we have the drug group here -- and we put a big D for the drug group and a big P for the placebo group -- and we take a look at the incidence of particular diseases. Let's say Disease A in both groups -- in both groups, and we're going to be looking for a relative risk. The Court has heard about relative risk. What do the -- what does relative risk reflect with regard to the results of an

epidemiological study of a drug?
A It simply reflects the rate of the disease in one group usually in a given period of time -- time is important -- versus the rate of disease -- same disease in the other group, same period of time.
Q If you have a relative risk of 1.0, what does that say about the frequency of the Disease A and the two groups, that is the drug group and the placebo group?
A No difference in frequency.
Q What if the drug group has 50 percent more? That is instead of -- let's assume that the placebo group has 100 cases of Disease A and the drug group has 150 cases of Disease A, what would the relative risk be?
A Again, same time frame. That would reduce to 1.5.
Q Okay, and under those circumstances what would you say about the -- whether Drug A carries with it -- based upon this one study whether Drug A carries with it a risk of disease?
A Well, one study is uusually not enough to establish causation, but putting that aside, it would say by itself that there's, as you put it, 50 percent more disease in one than the other that suggests that there is a risk with the drug that's -- that exceeds the background risk --
Q Okay.
A -- by 50 percent.
Q Under those circumstances what would you say about cause?

That is whether the Drug D can cause Disease A in some people.
A In some people, you'd say -- this is well established, and you've established the causation criteria, and this was statistically significant. You'd say that, yes, it would in some people cause disease.
Q What if it's 1.5, but it's not statistically significant?
A It would remain an association -- well, I guess -- I'm sorry. It would not remain an association. It would be -- you could not say with any confidence -- not statistically significant means you cannot with any confidence say it differs from one. That's basically what it means, and if that were the case, then it would be imprudent to conclude any causation or an effect there. Imprudent is what I said.
Q We've sometimes seen these confidence intervals where we have a relative risk of one and a risk that -- or a relative risk that reads out at say 1.5, so it's somewhere over here, indicating on the chart, and we see a confidence interval that's both -- it goes both above the point estimate and below the point estimate. What does the confidence interval stand for?
A Okay. The -- you have a measured value which comes from your study. That's the circle. The statistician is called in, because we know there's error always in every measurement. And this is basically a way to estimate the possible error, and a way to interpret the confidence interval is to say that within

that interval we can be sure with high confidence that the true value of the risk is somewhere in that interval, but we're not sure what the true value is, but we're confident it's in that interval.

Q Okay. If the confidence interval includes at either end one is the relative risk, what does that tell you about statistical significance?

A If it overlaps on the bottom end, one, that would say for this particular funding, given the error, we could not be confident with any degree of scientific certitude that the value, 1.5, was different from one. In other words, you'd say this is not a statistically significant finding.

Q Let's now change our hypothetical.

MR. BERNICK: Do we have a little eraser around here someplace?

(Pause)

Q Let's change the hypothetical a little bit and now assume that instead of having 100 cases of disease in the placebo group and 150 in the drug group, we now have 200 cases -- make it easier. We have 210 cases of Disease A in the drug group and only 100 in the placebo group. And let's further assume that this is replicated in high quality studies, so it's not just one study. It's a number of high quality studies. Under those circumstances, and it's statistically significant, what would the relative risk be?

A It's the ratio again, so that would be reduced 2.1.
Q Again under those circumstances what would you say about cause? That is does -- can Drug D in this group cause Disease A?
A Yes. Given all the conditions you laid out, I would say yes, it can cause.
Q Okay. I got that wrong. Yes. I want to ask you a series of questions about the implications of this. Are you familiar with the term doubling dose?
A I am.
Q And what doubling dose mean?
A Well, it means the dose of the causative agent that can be shown through this kind of epidemiology data to double the ordinary risk of the disease. You have a -- all these diseases have some background risk that we all have, and from the epi data, if you have a finding like this, you would say that the dose of this drug, whatever it was, was sufficient to double the risk -- a little more double it, so you'd call that dose a risk-doubling dose.
Q Now I then want to ask you some questions about what the implications of that result would be with respect to the individuals who take the drug. So I'm going to kind of blow this box up big and assume that the group of people who took that drug are all in the box, and let's say there are -- let's say that there are 500 individuals who took the drug. Does the

fact that you found or the study found an increased risk -- statistically significant increased risk of Disease A in this population of 500 people -- does that or does that not have any implications for those individuals?

A It does.

Q Can you tell us what the implications are for those individuals?

A The implications are the following. That you would conclude from the population itself, the finding of the study, that the 210 cases you have here -- that more than half of them, because we've doubled the risk now -- more than doubled the risk. More than have of those cases came from exposure to the drug rather than from the background. We don't know which specific cases, but we know that more than half of them arose from the drug. We -- to get to your question about the individual, what you would then say is that for each of the individuals in that group you could claim that it is -- that the disease they have is more likely to have come from the drug than from whatever it is that caused their background risk. In other words, they have a greater than 50 percent chance that the disease arose from the drug individually than from other causes.

Q So if we go through and we find out all 210 people who got sick would that same statement apply, that it is more likely than not drug related?

A Yes. No -- again we don't know with each individual, but you can say probabilistically for the group as a whole -- individually as a whole, I should say, that each one of them has a greater than 50 percent chance of having contracted the disease because of the drug.

Q Now, is there anything more that you could do by looking at them, examining them? These are all people taking the same drug, same dose. Is there anything more than an individual examination of those people could tell you that would establish which ones of those people got sick from the drug and which ones of the people got sick, because the disease happens in the general population?

A It depends on the drug and the effect. I mean it's possible that in some cases there may be alternative causes for individual people that are more explanatory than the drug. So that's another question that could be raised. If you --

Q Okay, so let me -- what you're saying is that there may be an alternative cause for disease. If the studies, however, controlled for the alternative cause -- that is made sure that either there was no alternative cause in either of the populations, or it was there for both populations, if this were controlled for in the studies, is there any way that an individual examination of these 210 people could establish which ones of them got sick from the drug and which ones of them got sick because of background conditions?

A Given your assumption that we could control for alternative causes, no, they would be a population then very much like the one studied. And no -- the answer to the question is no.

Q Now to anticipate have you in your report -- you had did a report in this case. Did you not?

A Yes.

Q And in your report it says at Page 9 of the report, "The assumptions and models used in regulatory risk assessments are not known to apply to any actual individuals but are rather generic in nature and apply only to certain hypothetical individuals who share common characteristics regarding their exposures and their potential sensitivities to asbestos." Remember making that statement under the heading saying, "Relevance of Regulatory Standards and Risk Assessments to Evaluation of Disease Causation in Individuals?"

A I do remember that statement, yes.

Q And do you remember that in your deposition you were asked about that sentence, and you said --

MR. FINCH: Your Honor, I object to the -- he hasn't been impeached of this. It's --

THE COURT: Sustained.

MR. FINCH: -- proper.

Q Let me ask you this question. When it comes to the regulatory risk models -- the regulatory risk models, can you